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Application Serial No. 10/522,110
Reply to Office Action dated January 21, 2010

JUL 21 2010

PATENT
Docket: CU-4057

REMARKS/ARGUMENTS

Reconsideration is respectfully requested.

Claims 1, 6-8, 12 and 21-34 are pending and are rejected. By the present amendment, claim 22 is amended to reference the complete name of CODPL. Claim 24 is also amended to correct a typographical error. No new matter has been added. The amendments to the claims can be viewed in the Amendments section of this paper in the Listing of claims beginning on page 2.

On page 2 of the Office Action, the Examiner indicates that an English translation of the priority document has not yet been received. The translation is not yet complete and will be submitted as soon as it is complete.

Claim 22 is rejected under 35 U.S.C. §112, second paragraph, for being indefinite. In response, the Applicant has amended claim 22 herein to recite the complete name of CODPL. The Applicant submits that this amendment is fully responsive to the rejection and respectfully requests that the Examiner withdraw this rejection of the claim.

Claim 24 is rejected under 35 U.S.C. §112, first paragraph, for failing to comply with the written description requirement. The Applicant submits that the amendment made to claim 24 correct a typographical error, as discussed above, is fully responsive to this rejection and respectfully requests that the Examiner withdraw this rejection of claim 24 as well.

In the office action (page 7), claims 1 and 34 are rejected under 35 U.S.C. § 103(a) as being obvious over JP 43-025506 to Yamabe et al. (IDS, June 8, 2009) in view of Okuda et al. (of record). Claims 6, 12, 23-26, 29 and 30 and 19 are rejected as obvious and unpatentable over Yamabe et al. in view of Okuda et al. in view of Remington's The Science and Practice of Pharmacy (PTO-892, Ref. U) in view of Goldenberg (U.S. 6,245,740) in view of Wicks et al. (U.S. 2002/0142972). Claims 7, 8, and 31-33 are also rejected under 35 U.S.C. § 103(a) as being obvious over

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Yamabe et al. in view of Okuda et al. in view of Remington's and further in view of Goldenberg in view of Wicks et al. and further in view of Holl et al. (U.S. 5,554,650).

The Applicant respectfully disagrees and submits that the claims are non-obvious and allowable.

The Examiner alleges that the results disclosed in Figures 2-5 of Table 1 of the previously submitted Declaration clearly show that the different degrees of laurate esterification on riboflavin does not significantly alter the properties of the compound. However, the Applicant disagrees.

It is clearly provided in Figures 4 and 5 of the Declaration that the 5'-laurate of riboflavin as claimed in the present invention has much better activity than that of the di-laurate or tri-laurate of riboflavin when intramuscularly administered. Such effect is hard to be derived or concluded from the prior art and thus is clearly not obvious to a person skilled in the art.

Furthermore, the Applicant provides a further set of experimental data indicating that the 5'-laurate of riboflavin as claimed has much less cytotoxicity in comparison with other riboflavin ester derivatives, e.g. 5'-caprate or 5'-myristate of riboflavin. It is another unexpected results of the claimed compound. See for instance the Declaration by Xu Qishou, paragraph 7, and attached results, after the last page of this paper. Moreover, the Applicant respectfully submits that the bioavailability of the 5'-laurate of riboflavin is even higher than that of riboflavin (6.4:6) when measured by weight gain after administration.

At least based on the above reasons, the Applicant submits that the claimed compound, preparation and method is non-obvious and allowable. The compound has proven unexpected effects including the better activity when intramuscularly

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administered and reduced toxicity.

The Applicant submits that at least for the reasons presented above, the compound, the oil suspension and the method as claimed in claims 1, 6-8, 12, and 22-34 are novel, non-obvious and allowable. The Applicant respectfully requests that the Examiner withdraw this rejection as to these claims.

The Applicant submits that this amendment is fully responsive to the January 21, 2010, office action. The Applicant requests that the amendments be entered into the record and further requests favorable consideration.

Respectfully submitted,

Dated: 7-21-2010


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